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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,694	03/14/2001	Anthony J. Kinney	BB1432 US NA	3560

23906 7590 09/24/2003

E I DU PONT DE NEMOURS AND COMPANY
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WILMINGTON, DE 19805

EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/24/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,694

Applicant(s)

KINNEY ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7 and 91-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7 and 91-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. The amendment filed 7/3/2003 has been entered.
Claims 1-3, 5-7, 91-96 are pending.
Claims 92-96 are newly added.
2. Claims 1-3, 5-7, 91-96 are examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Objection

Claims 6, 7, and 92-96 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot be dependent on a multiple dependent claim.

Indefiniteness

5. Claims 1-3, 5-7, and 91-96 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Rejection includes dependent claims.

In claims 1 and 3, the metes and bounds of “substantially” have not been defined. It is unclear to what degree said nucleic acid fragment corresponds to SEQ ID NO:1. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/12/2003.

Applicant’s arguments filed 7/3/2003 have been fully considered but they are not persuasive.

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Applicant did not address this rejection in the response and as such it is still maintained.

In claim 1, it is not clear if the "transcript" is in sense or antisense orientation given that Applicant is claiming a lower level of Gly m Bd 30 K₂ content.

Written Description

6. Claims 1-3, 5-7, and 91-96 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/12/2003. Applicant's arguments filed 7/3/2003 have been fully considered but they are not persuasive.

Applicants direct the Office to page 14, lines 12-23 as containing subject matter which fulfills the written description requirement and in addition, Applicants resubmit the Kalinski et al reference which reports on the deduced sequence of P34.

The Office contends that the above cited paragraph primarily states that P34 exhibits some conserved amino acids as compared to other members of the family but that it also exhibits unique amino acids. It is not clear which amino acids are unique and which are conserved so as to permit one skilled in the art to identify the multitude of sequences encompassed by the claims. Applicant does not disclose a representative number of sequences having 45% sequence identity with SEQ ID NO:1 to allow one skilled in the art to reliably determine the structure of sequences other than SEQ ID NO:1 as encompassed by the claims. Likewise, the Kalinski et al reference

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does not present an alignment or information that would be useful for determining mutants and allelic variants. Without a knowledge of all required and essential domains and/or amino acids, the Written Description requirement is not fulfilled for claims drawn to fragments corresponding substantially to a transcript encoding all or a part of Gly m Bd 30 K polypeptide.

Enablement

7. Claims 1-3, 5-7, and 91-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant expression construct comprising SEQ ID NO:1 transformed into soybean to lower the soybean vacuolar protein P34 content of a soybean, does not reasonably provide enablement for claims broadly drawn to a recombinant expression construct comprising a nucleic acid fragment corresponding substantially to a transcript encoding all or a part of Gly M Bd 30 K polypeptide and said isolated nucleic fragment shares at least 45% sequence identity with the nucleotide sequence set forth in SEQ ID NO:1 wherein the expression of said construct is sufficient to lower the Gly m Bd 30 K content and seeds comprising said construct. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/12/2003. Applicant's arguments filed 7/3/2003 have been fully considered but they are not persuasive.

Applicants contend that the specification does disclose how a plant transformed with any of the above mentioned sequences will suppress the expression of the endogenous allergenic protein (page 7, paragraph 5). Applicants reference Example 8.

The Office contends that Example 8 discloses using different promoters in expression constructs which are transformed into plants and said plants have lower α - or α' subunits, all of which are associated with altered oil content and not altered soybean vacuolar protein. Furthermore, neither Applicant's disclosure nor the state of the prior art teaches that gene silencing can be achieved with any sequence having 45% sequence identity with SEQ ID NO:1. It is more likely that a nucleic acid sequence exhibiting 45% sequence identity with SEQ ID NO:1 would encode an entirely different protein which would have no effect on Gly m Bd 30K levels in a plant. Applicant does not teach which regions of SEQ ID NO:1 must be conserved for gene silencing of Gly m Bd 30K. Absent such guidance, it would require excessive experimentation and undue burden for one skilled in the art to determine operable embodiments other than thru random trial and error.

Applicant presents references, WO 99/15682 and WO 99/53050, that describe methods for gene silencing.

The Office contends that Applicant is enabled for reduced levels of Gly m Bd 30 K content using SEQ ID NO:1, but based on the lack of guidance and examples using sequence fragments as claimed in claims 1 and 3 and given the presented art, as discussed in the previous office action mailed 3/12/2003, and given the claim breadth, it would require undue experimentation for one skilled in the art to make and/or use the broadly claimed invention.

Utility

8. Claims 91 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is maintained for the reasons of record set forth in

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the Official action mailed 3/12/2003. Applicant's arguments filed 7/3/2003 have been fully considered but they are not persuasive.

Applicants contend that the claim has been amended to recite that the seeds comprise the construct introduced into the parent plant.

The office contends that the amendment filed with the Office on 3/12/2003 does not recite said amendment.

9. No claims are allowed. SEQ ID NO:1 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 703-305-6997. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

September 22, 2003


PHUONG T. BUI
PRIMARY EXAMINER